I'm Andrew Bergman, and I'm speaking today as the special environmental advisor at the Project On Government Oversight, but I'm also currently a Ph.D. student in applied physics at Harvard University.

While the proposed "Strengthening Transparency in Regulatory Science" rule uses the words "transparency" and "reproducibility" to project lofty goals, it's real effect will be to undermine the way that the EPA is able to rely on and even-handedly assess scientific studies for use in the rulemaking process. I'm here today to urge EPA to withdraw this rule.

My colleague, Sean Moulton, has just addressed ~~will focus on~~ how the proposed rule conflicts with the EPA's regulatory process, and the statutory requirements underlying that process, but the rule will also have a direct impact on how the EPA approaches science.

The rule fails to properly address its two key considerations that will have a major impact on how it is implemented. First, the rule states that data relied on in making regulations must be made publically available, but it doesn't suggest a mechanism for how personally identifiable information or confidential business information would be handled.

This is an incredibly important issue, as so many studies that EPA uses rely on this type of confidential data. Yet it's reasonable to conclude from the rule that, if it goes into effect, the EPA will no longer be able to use most longitudinal human health studies to craft public safeguards, even though those studies have been conducted by reputable researchers at academic institutions, and peer reviewed to ensure validity. Instead, they will be left with industry studies that more often use animal test subjects, which don't have any personal privacy concerns.

Second, while the rule refers to replicability of scientific findings, the background information supporting the rule focuses on scientific studies' reproducibility, which has a wholly different meaning in a scientific context. But because the rule itself says it must be possible to "replicate" studies' findings, we should assume that the rule intends the strongest possible meaning: that it must genuinely be possible to conduct all studies used in rulemaking again, from scratch, and obtain the same findings.

The Agency uses many studies, however, such as those that link leaded gasoline to brain damage in children or a study that found a link between fine particulate air pollution and premature deaths, that examine dangerous real world exposures and cannot, of course, be safely repeated. Just because they can't—or shouldn't—be repeated, however, doesn't mean we should ignore the vital insights they provide. The knowledge we have gained from these tragedies can and should be used to help safeguard the public in the future.

Without knowing the details of how these two provisions, central to the rule, will be implemented, commenters can't even begin to assess the wide-ranging outcomes of this rule. We can conclude that the result will be that large swaths of studies will be arbitrarily ruled out for use in future rulemakings.

The rule's constraints on the use of scientific studies mean that even the use of studies that don't end up being haphazardly tossed out by this rule will be hindered substantially. The CBO found that a policy very similar to the proposed rule, when it was proposed as legislation, would significantly reduce the number of studies that EPA is able to rely on when issuing and proposing rules without a substantial input of funding—a major loss when Agency scientists already have the tools to conduct thorough assessments of studies they rely on.

The rule also puts the Agency in a position where it's forced to serve as an independent reviewer of all scientific data underlying studies it uses, which will again hamstring Agency scientists who have limited resources. When the EPA was sued over air quality standards for particulate matter and ozone during the George W. Bush administration, the U.S. Court of Appeals for the District of Columbia Circuit said a requirement to make public underlying data for the key studies used in rulemaking would be "impractical and unnecessary."

The three judge panel said: "If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment ..." Essentially, the judges concluded that a policy like the proposed rule wouldn't serve the Agency's purposes at all.

Instead of arbitrarily slicing out broad types of studies from being cited in rulemaking, why not continue to give Agency scientists the ability, as they have had for decades, to comprehensively assess and compare the scientific evidence presented in a study and give weight to each study as a result of careful deliberation.

If the EPA wants to address the accessibility of scientific studies and data, an important issue to scientists as well as members of the public, it should acknowledge that those efforts, which might include building a new public-facing platform or carefully considering certain types of standards, will amount to a years-long process and will require an enormous investment of Agency time and funding. That type of proposal shouldn't be made in a brief proposed rule and should only be made if extensive studies demonstrate that there is a real need for an update to how scientific studies are used in Agency rulemaking.

The proposed "Strengthening Transparency in Regulatory Science" rule, instead, gestures toward an unsubstantiated set of concerns. It's hard to conclude that its purpose is to do anything other than undermine Agency scientists' ability to use scientific studies and data to craft regulations, under EPA's statutory mandates, that protect public health. For this reason, I urge you again to withdraw the rule.

Thank you for your time and for the opportunity to comment on this important proposal.